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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/666,252	03/08/91	WALL	6 50112

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EXAMINER

LOM, C

ART UNIT

PAPER NUMBER

1814

13

DATE MAILED: 07/17/92

07/17/92

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined *for the purpose of restriction* ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____  |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-59 are pending in the application.  
Of the above, claims 1-59 are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☒ Claims 1-59 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Restriction to one of the following inventions is required under 35  
U.S.C. 121:

- I. Claims 1-18 and 29-41, drawn to a mammalian recombination system containing DNA wherein transformed host cells and non-human transgenic animals contain the DNA, and method of assembling functional genes are classified in Class 435, subclasses 320.1, 240.2, 172.3 and Class 536, subclass 27, and Class 800, subclass 2.
- II. Claims 19-23, drawn to a method of disrupting gene function so as to prevent inactivation of expression are classified in Class 435, subclass 172.3.
- III. Claim 24, drawn to obtaining DNA from the genome of a transfected organism containing tandemly oriented FLP target sites is for example classified in Class 435, subclass 91.
- IV. Claims 25-28 and 42-55, drawn to a method of precisely targeted integration of DNA in cells (claims 25-28 and 42-48) and non-human transgenic animals (claims 25-28 and 49-55) are for example classified in Class 435, subclass 172.3
- V. Claims 56 and 57, drawn to a method for analysis of mammalian development are classified in Class 435, subclass 4.
- VI. Claims 58 and 59, drawn to a cotransfection assay are classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and of II, IV, V, and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the DNA can be used as a probe as opposed to the process gene disruption disclosed in Group II or the gene targeting set forth in the claims of Group IV or in bioassays as in indicated in Groups V and VI wherein Groups II, IV, V, and VI are alternative processes of use.

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The inventions of Group III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the DNA of Group I can apparently be obtained by the alternative process recited in the claims of Group III or by traditional chemical synthesis.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification, subject matter, and are separately and independently searched, restriction for examination purposes as indicated is proper.

A telephone conversation on 13 July with Steven E. Reiter did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

An inquiry concerning this communication should be directed to Christopher Low at telephone number (703) 308-0196.

CSFL  
15 July 1992

*Christopher S.F. Low*  
CHRISTOPHER S.F. LOW  
PATENT EXAMINER  
GROUP 180